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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Cetin Gurses

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EXAMINER

SHOME, ARUNDIPTA

ART UNIT

PAPER NUMBER

4116

NOTIFICATION DATE

DELIVERY MODE

05/14/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/500,921	Applicant(s) GURSES, CETIN	
	Examiner ARUNDIPTA SHOME	Art Unit 4116	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004 and 09 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/08/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In response to the Preliminary Amendment filed on July 8, 2004 and November 9, 2005, claims 1-8 and the newly added claims 9-14 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 5, the phrase “electronic interphase” is indefinite and unclear.

Claims 6-8 are rejected for incorporating the above errors from their respective parent claims by dependency.

Claims 7 and 8 are also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 7 and 8 have not been further treated on the merits.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art and Lavigne et al (US Patent No. 5,533,514) in view of Horch et al (US Patent No. 5,022,407).

Regarding claim 1, Applicant's admitted prior art disclosed in the specification (Page 7) states that: "GT receptors which are exposed to the pressure of PSP cycles in muscle fibres reflect themselves right away with a pointing, very sharp, burning pain feeling when the skin layer above them is stimulated even by a feathery, light touch. This pain is referred to as Golgi tendon (GT) specific pain in GNT terminology. The first pressure value at which this specific pain is first felt by the patient and over which the pain increases with the increase in applied pressure is defined as "GT Pain Pressure Threshold." Clearly, a low GT pain pressure threshold value and the numerously high amount of similar GT points give definite information as to the amount and the intensity of PSP cycles on the muscle." Therefore, this shows that a device capable of pain sensitivity pressure measurements would also be capable of locating Golgi tendons because a sharp burning pain would be indicative of a location of a Golgi tendon.

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Lavigne et al teaches a pain sensitivity measurement system comprised of a pressure algometer instrument for measuring pressure values applied (Abstract) and a computer (Figure 1) with a display system (13). The computer system stores pressure values to a file associated with the patient (abstract) and can also print the results of the evaluation (column 6, line 8). Lavigne et al also discloses a pressure algometer with a pressure applying tip 18. Lavigne et al also discloses means for “when the patient indicates that a threshold of pain has been reached by depressing a push-button connected to the algometer” (column 2, line 26). Lavigne et al does not disclose any kind of vibratory means for use with the algometer instrument. However, Horsch et al et al discloses an apparatus for testing tactile responses of a patient. This apparatus comprises means for indenting the patient’s skin to test the patient’s response to touch and vibrating the patient’s skin to test the patient’s response to vibration. (Abstract). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the elements of Lavigne et al and the vibratory element of Horsch et al. This is because, as stated in the specification of Horsch et al, “Many medical professionals need to determine a patient’s response to various modes of tactile stimulus. For example, medical professionals dealing with the human nervous system often need to determine a patient’s response to various tactile stimuli to assess the extent of any damage to the nervous system due to trauma or regenerative condition” (column 1, line 19). In this case, combining the elements disclosed in Lavigne et al with means for vibrating a patient’s skin known in the art yields the invention claimed here.

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Regarding claim 2, Lavigne et al teaches an analog/digital converter (Fig. 1) and a computer system (2) connected to the algometer for storing input data from the algometer to a file.

Regarding claim 3, Fig. 1 of Lavigne et al teaches a program memory (3), and means for compilation of the collected data and storing the data in the program memory. (column 5, line 57).

Regarding claim 4, Fig 1 of Lavigne et al teaches a computer system (2) for use with the algometer. A computer is capable of processing data and must contain a processor. The system from Lavigne et al is designed for identifying pain pressure points and pain thresholds. A display unit (13) is also disclosed in Lavigne et al to display results and information, and the computer can also print the results of the evaluation carried out.

Regarding claim 5, as best interpreted, Fig. 1 of Lavigne et al discloses an A/D converter (5) which converts the signal from the algometer to a digital form and transmits this to the computer (column 4, line 43).

Regarding claim 8, Lavigne et al discloses a pressure algometer used by an operator to apply pressure to various points on a patient's skin surface (Abstract). Applying pressure to the skin's surface will also apply pressure to the golgi tendon receptors beneath the skin.

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6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art and Lavigne et al (US Patent No. 5,533,514) in view of Horch et al (US Patent No. 5,022,407) and further in view of Law et al. (US Patent 5,938,690)..

Regarding claim 6, Lavigne et al discloses a program memory (3) (Fig. 1), and means for compilation of the collected data and storing the data in the program memory. It is noted that the teachings of Lavigne et al and Horch et al do not specifically disclose an algometric map or pain map of the human body. However, Law et al. discloses a system that comprises "a computer database of information in connection with the pain map of an individual patient" (see Abstract and from column 2, line 44 to column 3, line 35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the pain map disclosed in Law with the memory disclosed in Lavigne et al and Horch et al to create algometric maps of patient's pain sensitive areas. This is because measured pain sensitivity values could be compared to a baseline for normal human pain sensitivity values for diagnostic purposes.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art and Lavigne et al (US Patent No. 5,533,514) in view of Horch et al (US Patent No. 5,022,407) and further in view of Oscar (US Patent No. 2,122,556).

Regarding claim 7, the teachings of Lavigne et al and Horch et al do not disclose a spherical tip for the algometer. Oscar discloses a vibratory massager with a spherical massaging portion. It is obvious to one of ordinary skill in the art to combine a spherical shaped tip with the algometer instrument of Lavigne et al and Horch et al because a

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spherical shape allows for more efficient movement of the tip over the surface of a patient's skin. As to the size of the spherical tip, MPEP 2144.04 states that "In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

8. Claims 9-14, and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art and Lavigne et al (US Patent No. 5,533,514) in view of Oscar (US Patent No. 2,122,556).

Regarding claim 9, Lavigne et al teaches a method of selecting points on a patient's body on which pain sensitivity measurements can be made by an operator (from column 1, line 43 to column 2, line 36). This is equivalent to the claimed method because as disclosed in page 7 of applicant's specification, as specifically in applicant's admitted prior art noted with respect to claim 1. Lavigne et al also teaches a method for measuring the pain threshold being reached by the patient depressing a button connected to the algometer. Lavigne et al further teaches a method for applying pressure to points until a pain threshold is reached. It is noted that Lavigne et al does not specifically disclose a spherical tip attached to the algometer/tensiometric instrument. However, Oscar discloses a vibratory massager with a spherical massaging portion. It would have

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been obvious to one of ordinary skill at the time the invention was made in the art to combine a spherical shaped tip with the algometer instrument of Lavigne et al because a spherical shape allows for more efficient movement of the tip over the surface of a patient's skin.

Regarding claim 10, Lavigne et al teaches an A/D converter for converting algometer readings into a digital format suitable for use by a computer which contains a microprocessor. Lavigne et al also discloses a computer with a display system (13) for display of results.

Regarding claim 11, Lavigne et al teaches a system for receiving and storing information on pain sensitivity measurements gathered from a patient in a digital format in the memory (3).

Regarding claim 12, Lavigne et al teaches means for receiving and storing pain sensitivity data in a memory (3) recorded from the algometer. Predetermined Golgi tendon inhibition pressure thresholds are not disclosed in Lavigne et al as being stored in the memory, but this element is obvious because the claim recites merely the act of using this predetermined data.

Regarding claim 13 Lavigne et al discloses a computer system (2) with a processor that would be capable of processing input data on pain threshold point data received from the algometric instrument to identify pain thresholds and pain inhibition thresholds. Lavigne et al also discloses a display (13) to display results from the algometer and the computer.

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Regarding claim 14, Lavigne et al does not explicitly disclose a method of calibrating the algometer instrument. However, it is obvious to one of ordinary skill in the art to have a calibration method for the instrument because all measuring instruments must be calibrated in some way to ensure accuracy of measurement. Additionally, Lavigne et al does disclose a method of applying a range of pressure values. Lavigne et al specifically discloses that “when the patient indicates that a threshold of pain has been reached by depressing a push-button connected to the algometer” (column 2, line 26). This implies that a range of increasing pressure values are applied to the patient’s skin.

Regarding claim 16, Lavigne et al discloses a method of applying a range of pressure values. Lavigne et al specifically discloses that “the patient indicates that a threshold of pain has been reached by depressing a push-button connected to the algometer” (column 2, line 26).

9. Claim 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant’s admitted prior art and Lavigne et al (US Patent No. 5,533,514) in view of Oscar (US Patent No. 2,122,556) and further in view of Horch et al (US Patent No. 5,022,407).

Regarding Claim 15, it is noted that the teachings of Lavigne et al and Oscar do not specifically disclose a vibration means. However, Horch et al et al discloses vibration means for vibrating a patient’s skin having a vibratory means driven and controlled by electrical circuitry which allows for the turning the vibrator on or off. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the algometer instrument of Lavigne et al and Oscar with the vibratory

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means in Horch et al because as stated in the specification of Horch et al, "Many medical professionals need to determine a patient's response to various modes of tactile stimulus. For example, medical professionals dealing with the human nervous system often need to determine a patient's response to various tactile stimuli to assess the extent of any damage to the nervous system due to trauma or regenerative condition" (column 1, line 19).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure.

Fowler et al. (US Patent No. 5,370,672) teaches a computer controlled neurological stimulation system that alleviates chronic pain. Lavigne et al (US Patent No. 5,592,947) teaches an algometer with pressure intensification rate adjusting and control capabilities. Shimazu et al (US Patent No. 6,113,552) teaches a pain measurement system and method. Lange et al. (US Patent No. 6,751,499 B2) teaches methods, apparatuses and systems relating to the objective measurement of the subjective perception of pain in a subject.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is

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(571)270-5539. The examiner can normally be reached on Monday through Friday 8:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Cheng can be reached on 703-272-4433. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARUNDIPTA SHOME/
April 28, 2008

/Joe H Cheng/
Supervisory Patent Examiner
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